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vitro dissolution study in three different solvents such as hydrochloric acid pH 1.5, artificial saliva pH 6.7 and saline phosphate buffer solution pH 7.4 respectively. And drug release from the *in vitro* dissolution study. **RESULTS:** The result reveals that prepared formulation F6 shown maximum value. The *ex vivo* permeation studies of Fluconazole drug through porcine buccal mucous membrane were performed and the results shown that F6 formulation was the best formulation among the prepared mouth dissolving tablets. **CONCLUSIONS:** Thus, the prepared (F6 formulation) mouth dissolving tablets had both local and systemic action and may be used for treating oropharyngeal and esophageal candidiasis (oral candidiasis) mainly as ulcer, burning sensation of buccal cavity particularly in premature infants, geriatric bed ridden patients, and patients with weak immune system caused by cancer treatment or diseases such as AIDS.

PCN44

TIME TO REIMBURSEMENT FOR ONCOLOGY AGENTS FROM EMA MARKETING AUTHORIZATION TO AIFA APPROVAL AS "C(NN)" CLASS VERSUS. AIFA APPROVAL AS "A" OR "H" CLASS

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OBJECTIVES: The purpose of this study was to evaluate the reduction in average market entry timelines for oncology agents in Italy if approved by AIFA as "C(nn)" class (non-negotiated class under the 189/2012 law) as compared to "A" (fully reimbursed) / "H" (hospital reimbursement). **METHODS:** For the purpose of this study, only the approval of the agents' first indications were taken into consideration. Included in this study were C(nn) oncology agents approved between May 27, 2013 and February 27, 2014 (aflibercept, pertuzumab, bosutinib, enzalutamide, vismodegib, pomalidomide, regorafenib, dabrafenib, infliximab, afatinib, radium Ra223 dichloride, trastuzumab emtansine) and class "A" / "H" agents approved between May 27, 2010 and December 2, 2013 (everolimus®, denosumab, pazopanib, cabazitaxel, denosumab, abiraterone, vemurafenib, vandetanib, axitinib). The average time to approval was calculated as the average difference between the date of issue of EMA marketing authorization and the determination date ("*determina*") in the Italian "*Gazzetta Ufficiale*". **RESULTS:** The average time to reimbursement for oncology agents from EMA marketing authorization to AIFA approval as "C(nn)" class was estimated as 111.3±39.9 days (n=12), while the average time to reimbursement as either "A" or "H" class was estimated as 428.3±109.0 days (n=9). This represents a significantly faster approval process (unpaired t-test, $p<0.01$), where on average, the C(nn) approval process is faster by 317 days. **CONCLUSIONS:** This study shows that time to reimbursement for oncology agents from EMA marketing authorization to AIFA approval is significantly expedited through the use of "C(nn)" classification, reducing market entry timelines by nearly a full year (317 days) compared to the regular "A" or "H" class approval process. Pharmaceutical companies seeking expeditious market entry into Italy for a newly approved oncology therapy targeting an area of high unmet need should therefore consider applying for C(nn) class.

PCN45

COVERAGE DECISION FRAMEWORK IN ASIA PACIFIC: A CASE STUDY OF TARGETED CANCER MEDICINES IN THE TREATMENT OF BREAST CANCER

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OBJECTIVES: To optimize access to cancer therapy in Asia Pacific (AP) nowadays became challenging due to budget constraints. Different decisions were made due to individual context, health care system and evidence required to support the decision. This study reviewed coverage decisions made by government in AP using targeted cancer medicines as a case study. **METHODS:** We selected 6 targeted cancer medicines recommended for breast cancer treatment based on the 2013 national comprehensive cancer network guidelines. Eight AP countries with different health coverage system were included to highlight the differences of health coverage system on decisions: four reimbursement countries [Australia (AUS), South Korea (KE), Taiwan (TW) and Japan (JP)] and four partial reimbursement countries [Malaysia (MY), Thailand (TH),China (CN) and Hong Kong (HK)]. We identified data from multiple sources including "Pubmed", government websites, payers and companies from inception till Jan 2014. We compared health coverage features, oncology coverage list and evidence requirement for decision making. Based on HTA approach, six possible supporting factors were compared. They included burden of disease, clinical effectiveness, economic evaluation (EE), budget impact analysis (BIA), public health impact, ethical concern and availability of alternative treatments. **RESULTS:** Efficacy and safety data were used as decision factors in all countries. AUS, KE, TW and TH considered both EE and BIA. AUS, KE and TH required local HTA evidence .Of six medicines, trastuzumab is now covered in most countries: AUS, MY, TW and KE. However, limited information is publicly available on evidence used in coverage decision in most countries except AUS where all factors except public health impact and ethical issue consideration are documented. **CONCLUSIONS:** Coverage decisions are affected by health care system and HTA evidence. Limited public documents related to coverage decisions are available. HTA system may lead to the development of explicit decision framework criteria for coverage decisions.

PCN46

THE INCIDENCE, PREVALENCE, AND SURVIVAL OF MALIGNANT MELANOMA IN TAIWAN

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OBJECTIVES: To understand the incidence, prevalence, and survival probability in the whole population in Taiwan. **METHODS:** This study utilized the 2005 to 2011 National Health Insurance (NHI) Research Database to study the disease. Inclusion criterion was that patients had at least two outpatient visits or one inpatient stay for melanoma (ICD9 code: 172). Patients' medical orders for outpatient visits and inpatient stay were linked. Their overall survival data were presented as product-limit survival probabilities. **RESULTS:** There were 240 to 290 new cases annually between 2006 and 2011. The raw incidence rate was about 1.1 to 1.26 per 100,000 persons,. The age adjusted incidence rate was around 1.5 per 100,000 persons. This was much lower than that the overall incidence in the US (21.1 per 100,000 per year). But it was similar to that of Asia-Pacific islanders in the US. The proportion of death between 2006 and 2011 were 28.8% and 21.9% among males and females respectively. This was different from the US population, whose 5 year survival was 91.3%. The population composition of the US was different from that in Taiwan and thus cannot be compared directly. About 29% of Taiwan patients were farmers. The mortality of farmers (36.5%) was slightly higher than that of non-farmers (22.4%). After controlling for age and sex, the hazard ratio of farmer vs. non-farmers was 1.136. Their age of diagnosis was much higher than the non-farmers: 82% and 34% for farmers and non-farmers diagnosed at age 65 and above, respectively. **CONCLUSIONS:** Malignant melanoma is found to be a rare but deadly disease in Taiwan. One reason for low survival probability was that farmers delayed the diagnosis to old age. It is suggested to screen farmers in early age.

PCN47

HOW SINGLE ARM PHASE II DATA CAN SUPPORT REIMBURSEMENT FOR ONCOLOGICS IN AUSTRALIA

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OBJECTIVES: The Food and Drug Administration (FDA) have approved 28 oncologics across 37 indications on the basis of pivotal Phase II data lacking an active comparator (Macaulay, ISPOR Toronto 2014). Approval was typically granted for indications with therapeutic alternative where a response rate ≥10% was demonstrated. This research aims to define the circumstances under which oncologics can obtain both regulatory approval and public reimbursement in Australia on this basis. **METHODS:** Public Summary Documents (PSDs) were extracted for any oncologic indication appraised by the FDA on pivotal Phase II data and the Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Advisory Committee (PBAC) decision and key rationale were extracted. **RESULTS:** 3 oncologics across 7 oncology indications (nilotinib in chronic myelogenous leukemia, dasatinib in acute lymphoblastic leukaemia (ALL), imatinib in ALL, dermatofibrosarcoma protuberans, myelodysplastic syndrome/ myeloproliferative disease and hypereosinophilic syndrome and/or chronic eosinophilic leukemia, and aggressive mastocytosis) have been granted TGA and PBAC approval on pivotal Phase II data. 2 were TGA approved but PBAC rejected (bevacizumab and cetuximab), 3 were submitted to PBAC on Phase III data, and no PSDs were extractable for the remaining 26 indications. In 7/7 approved indications, PBAC recognized active comparator alternatives. In 4/7, the rarity of these indications was cited as a key mitigating factor. For 2/7, overall survival (OS) data was presented that indicated potentially substantial OS benefits. In 1/7, a cost-minimisation argument was accepted against a recently approved comparator. Of the PBAC-rejected drugs, cetuximab raised key concerns over a lack of OS data, while significant trial comparability issues were expressed with bevacizumab. All PBAC-approved submissions included economic modelling on a cost/benefit, not cost/QALY, approach. **CONCLUSIONS:** PBAC can recommend the reimbursement of oncologics that offer potentially substantial clinical benefits based on an indirect comparison of single arms trials with acceptable cost-effectiveness as demonstrated on a cost-benefit metric.

PCN48

QUALITY CONTROL OF THE HUNGARIAN NATIONWIDE MAMMOGRAPHY SCREENING PROGRAMME

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OBJECTIVES: Organised, nationwide screening for breast cancer with mammography in the age group 45-65 years with 2 years screening interval started in Hungary in January 2002. According to the Hungarian guideline on mammography screening, an accredited mammography screening centre should perform 10000 examinations annually. The aim of this study is to analyze the quality control indicators of this screening programme. **METHODS:** The data derive from the financial database of the National Health Insurance Fund Administration (NHIFA) covering the period 2002-2010 year. We analysed 3 selected years: 2002, 2005 and 2010. The main indicator was the number of mammography screening examinations performed by the mammography screening centres. **RESULTS:** The annual number of mammography examinations was 323537 in 2002, 247045 in 2005 and 242601 in 2010. The number of accredited mammography screening centres were 51 (2002), 41 (2005) and 40 (2010). The average number of mammography examinations were 6344 (2002), 6025 (2005) and 6065 (2010) per year. In 2002, 14 mammography centres performed 10000 examinations in a range from 10314 to 25940. In 2005 only 4 mammography centres achieved more than 10000 examinations per year (range: 10294-17845). In 2010 again only 4 mammography centres achieved more than 10000 examinations per year (range: 10239-19259). **CONCLUSIONS:** Only a few number of mammography centres met the recommendation of the Hungarian mammography screening guideline and reached the target (10000 mammography examinations annually). Most of the mammography centres are not able to comply with professional guideline.

DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1

INCRETIN THERAPY AND RISK OF PANCREATITIS IN TYPE 2 DIABETES MELLITUS: SYSTEMATIC REVIEW OF RANDOMIZED AND NON-RANDOMIZED STUDIES

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